

Diabetic Peripheral Neuropathy and its Risk Factors among Chronic Diabetic Patients in Southern Karnataka, India

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ABSTRACT

Background: The global prevalence of diabetes mellitus (DM) was 10.5% (2021). The common complications of DM include diabetic peripheral neuropathy (DPN) which affects 30% to 50% of diabetics. DPN is a debilitating complication of diabetes that significantly impairs the quality of life of individuals. **Objectives:** To estimate the magnitude of DPN using Michigan Neuropathy Screening Instrument (MNSI) and to determine the factors associated with it.

Methodology: A facility based cross-sectional study was conducted among 100 participants with diabetes for more than 5 years. Questionnaire included sociodemographic details, diabetes history, co-morbidities, personal habits, MNSI patient and clinical version for detecting DPN. Bivariate analysis was performed to determine the factors associated with DPN; multivariate analysis to determine the exact factors affecting DPN.

Results: Proportion of DPN was 34% & 38% on MNSI interview and examination version respectively. Factors affecting DPN were age, tobacco consumption, age of diagnosis of DM, co-morbidities on bivariate analysis. Tobacco consumption [AOR- 6.72, CI-2.07-21.8, P=0.002] & co-morbidities [AOR- 7.19, CI-1.93-26.7, P=0.003] on multivariate analysis.

Conclusion: Proportion of DPN remains high among individuals with diabetes. Smoking & presence of co-morbidities contributes to an increased risk of DPN.

Keywords: Diabetic Peripheral Neuropathy, Michigan Neuropathy Screening Instrument, Risk factors, Tobacco, Multivariate-analysis

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INTRODUCTION

The global mortality trend is shifting from infectious diseases to chronic conditions, commonly referred to as non-communicable diseases (NCDs) which accounts for 70% of all deaths. They emerge as a consequence of genetic, physiological, environmental, and behavioral factors.¹ Coronary artery disease, stroke, cancers, chronic respiratory diseases, and diabetes mellitus are prominent non-communicable diseases of considerable public health importance.²

Diabetes mellitus has become a global epidemic, impacting millions of individuals worldwide. The rise in diabetes prevalence can be attributed to various factors like inactive lifestyles, unhealthy eating habits, obesity and aging of the population.³

The estimated global prevalence of diabetes in individuals was 10.5% in 2021, affecting 536.6 million among people aged 20 to 79 years.⁴ Projections suggest a rise to 643 million by 2030 and a further rise to 12%, impacting 783.2 million individuals by 2045. It leads to 6.7 million deaths, with one occurring every five seconds.⁵

74.2 million people are affected with diabetes in India, second highest worldwide, with estimations up to 124.8 million by 2045.⁴ The progress in reducing the burden of the disease is hindered due to failure of early diagnosis seen in cases of diabetes.⁶ Many are aware of their diabetic status only after they land up in complications related to diabetes.⁷

The common complications of DM include diabetic retinopathy, nephropathy, microvascular complications and neuropathy. It is estimated that 30% to 50% of diabetes patients are affected by diabetic peripheral neuropathy (DPN) which is defined as a "symmetrical, length-dependent sensorimotor polyneuropathy attributable to metabolic and microvessel alterations as a result of chronic hyperglycemia exposure".⁸

Its prevalence is expected to increase significantly in parallel with the rising diabetes epidemic.⁷ The impact of DPN on individuals extends beyond physical symptoms, often resulting in significant functional limitations, reduced mobility, decreased productivity, and increased healthcare costs. Furthermore, DPN increases the risk of foot ulcers, infections, and lower extremity amputations, emphasizing the urgent need for effective prevention and management strategies. To develop targeted interventions, it is crucial to identify and understand the determinants that predispose individuals to DPN, allowing for personalized treatment approaches and improved patient outcomes.^{5,9}

DPN is a debilitating complication of diabetes that significantly impairs the quality of life of individuals.¹⁰ Understanding the magnitude of DPN and its determinants is essential for addressing its substantial burden on individuals, healthcare systems, and society. Similar studies have been conducted in

coastal part of Karnataka.^{6,11} whereas, there is a paucity of literature in this part of Karnataka, an effort was made to fill the gap by the following objectives to estimate the proportion of Diabetic Peripheral Neuropathy among diabetics using Michigan Neuropathy Screening Instrument (MNSI) and to determine the factors associated with it.

METHODOLOGY

Study design and study setting- A facility based cross-sectional study was conducted for six months, from July to December 2023 which focused on patients with type-2 diabetes mellitus (DM) who attend outpatient clinics (OPDs) and Inpatient department (IPDs) of the Government Hospital, Gundlupet Taluk, belonging to Chamarajanagar, Karnataka. 100 to 200 patients visit OPD Every day, 50 to 60 of whom will need follow-up care for diabetes.

Records of all diabetic patients are maintained in the NCD clinic of the hospital as per the norms of National Program for Prevention and Control of Non-Communicable Diseases (NP NCD) program.

Study subjects - Patients with type 2 diabetes mellitus who had been diagnosed for longer than five years were included in the study. After considering the reference study conducted by MD Abu Bashir in the year 2020⁹, prevalence of DPN was 42%, taking a power of 80%, absolute precision of 10% and confidence level of 95%, using the formula,

$$n = \frac{Z_{1-\alpha/2}^2 P(1-P)}{d^2},$$

the minimum estimated sample size was 94, which was approximated to 100. The study subjects were selected using convenient sampling.

Study tool - A semi-structured questionnaire was developed by incorporating insights from a thorough literature review and experts' opinion in the field of diabetes. The questionnaire comprised four sections, which included the socio-demographic profile, diabetes history and co-morbid conditions, personal habits of the study participants and Michigan Neuropathy Screening Instrument (MNSI) tool¹².

The MNSI is a validated screening tool for DPN in both community and hospital settings. It comprises two parts: the first part includes the patient's perception of their symptoms related to DPN, and the second include tests to identify patients who have DPN.

The first part of the MNSI questionnaire asks participants whether they have DPN symptoms or not. A higher score (out of a maximum of 13 points) indicates more neuropathic symptoms. Responses of "yes" to items 1-3, 5-6, 8-9, 11-12, 14-15 are each counted as one point. A "no" response on items 7 and 13 counts as 1 point. Item 4 is a measure of impaired circulation and item 10 is a measure of general anesthesia and they are not included in scoring. The

overall score is calculated by adding all of the responses. A cumulative score of 7 was considered positive for the DPN.

The second part include three tests:

i) vibration sensation test using a 128 Hz tuning fork, vibration is present if the examiner senses the vibration on his or her finger for less than 10 sec than the subject feels it in the great toe, decreased if sensed for ≥ 10 s (scored as 0.5) or absent (scored as 1)

ii) elicitation of muscle jerk reflex at the ankle joint, if the reflex is absent, the patient is asked to perform the Jendrassic manoeuvre and, if present, the reflex is present with reinforcement and is scored as 0.5. If the reflex is absent with the Jendrassic manoeuvre, the reflex is designated as absent and is scored as 1.

iii) monofilament testing, 8 correct responses out of 10 applications are considered normal: 1 to 7 correct responses indicate reduced sensation (scored as 0.5) and no correct responses gets score of 1. Each foot is also inspected for ulcers and each foot with an ulcer is scored as 1. Maximum score of 8 points, a cumulative score of ≥ 2.5 was considered positive for the presence of DPN. The investigator performed the examination for all participants in a separate examination room¹².

Patients were recruited in line with our inclusion criteria and the duration of diabetes was reconfirmed with the patients record at the NCD clinic of the hospital. After explaining about the study procedure, potential risks and benefits, participants willing to participate were included in the study. First three sections and first part of MNSI which included questionnaire were asked to the patients by the researcher, second part of MNSI i.e., the examination part was conducted in the separate examination room by the same investigator who is pursuing a medical post-graduate degree and was also imparted training under the supervision of the experts in the field. The study was conducted by the investigator after necessary trainings only which helped to maintain uniformity throughout the data collection process.

Statistical analysis - Data collected was entered in MS-Excel and analyzed using Statistical Package for Social Sciences (SPSS) version 16 (Chicago, IL, USA). Descriptive statistics like proportion of DPN, proportion of tobacco consumption & alcoholics were expressed in terms of percentages & presented in tables. Analytical statistics like association between socio-demographic variables and clinical variables were done using bivariate analysis (Chi-square test). P-value < 0.05 was considered to be statistically significant. Unadjusted and adjusted odds ratio with 95% CI were done to find the likelihood of the above factors with DPN. The variables which were found to be significant on bivariate analysis were subjected for multiple logistic regression.

Ethical considerations - Approval from Institutional Ethics Committee of Chamarajanagar Institute of

Medical Sciences, Chamarajanagar (Approval letter number-CIMS/IEC-02/22/2023 and date of approval-25/10/2023) was obtained prior to the start of the study. An informed consent was obtained from all the study participants before the initiation of interview as well as examination.

RESULTS

The current study was done on 100 participants who were diabetic for more than 5 years. Among them 58% were males and 48% were females. Majority belonged to rural locality (72%). The remaining socio-demographic details of the participants have been provided in Table 1.

35% of the participants were found to be consuming tobacco, alcohol consumption habit was found in 10% of the participants. Age at diagnosis of diabetes was >45 years among 74 %, ≤ 45 years among 26%, Majority were on oral anti-diabetic treatment (82%). Majority (61%) presented with one or other comorbidities like Hypertension, Cardiac diseases, Asthma, Renal diseases. (Table 2).

Table 1: Baseline characteristics of the study participants

Baseline Characteristics	Cases (n=100) (%)
Age group(years)	
>55	70 (70)
≤ 55	30 (30)
Gender	
Male	58 (58)
Female	42 (42)
Locality	
Rural	72 (72)
Urban	28 (28)
Marital status	
Married	72 (72)
Widow/widower	27 (27)
Unmarried	1 (1)

Table 2: Risk factors for Diabetic Peripheral Neuropathy (n=100)

Parameter	Cases (%)
Tobacco consumption	
Present	35 (35)
Absent	65 (65)
Alcohol consumption habit	
Present	10 (10)
Absent	90 (90)
Age at diagnosis of diabetes mellitus	
>45 years	74 (74)
≤ 45 years	26 (26)
Current medication for Diabetes	
Oral anti-diabetics	82 (82)
Insulin	9 (9)
Both	9 (9)
Co-morbidities (Hypertension, Cardiac diseases, Asthma, Renal diseases)	
Present	61 (61)
Absent	39 (39)

Results based on Michigan Neuropathy Screening Instrument history (patient version)

Based on the scoring of MNSI patient version, the prevalence of DPN was found out to be 34% (n=34). Table 3 presents the factors associated with diabetic peripheral neuropathy on MNSI history version. On binary logistic regression, age, tobacco consumption, presence of co-morbidities was found to be significant risk factors for DPN. The corresponding Odds ratios and confidence intervals have been mentioned in detail in Table 3.

Results based on Michigan Neuropathy Screening Instrument examination version

The prevalence of Diabetic Peripheral Neuropathy was found to be 38% (n=38) among the study participants on MNSI examination version. On binary logistic regression, age, tobacco consumption, age of diagnosis of DM & presence of co-morbidities were found to be significant risk factors for DPN. The corresponding Odds ratios and confidence intervals have been mentioned in detail in Table 4.

Table 3: Factors associated with DPN in MNSI patient interview version (n=34)

Factors	DPN Present N=34 (%)	DPN Absent N=66(%)	Chi-square test	p-value (χ^2)	Unadjusted Odds Ratio (95% CI)
Age					
>55 years	30 (88)	40 (61)	8.15	0.05*	4.87 (1.5-15.4)
≤55 years	4 (12)	26 (39)			Ref
Age of diagnosis of DM					
>45 years	29 (85)	45 (68)	3.41	0.065	2.70 (0.91-7.98)
≤45 years	05 (15)	21 (32)			Ref
Alcohol consumption					
Present	03 (9)	07 (11)	0.07	1	0.81 (0.19-3.37)
Absent	31 (91)	59 (89)			Ref
Co-morbidities					
Present	30 (88)	31 (47)	16.06	<0.001*	8.4 (2.6-26.7)
Absent	04 (12)	35 (53)			Ref
Gender					
Male	24 (70)	34 (52)	3.35	0.08	2.25 (0.93-5.45)
Female	10 (30)	32 (48)			Ref
Locality					
Rural	25 (73)	47 (71)	0.06	1	1.12 (0.44-2.84)
Urban	09 (27)	19 (29)			Ref
Tobacco consumption					
Present	21 (62)	14 (21)	16.22	<0.001*	6.0 (2.4-14.8)
Absent	13 (38)	52 (79)			Ref

* = P-value <0.05 is considered to be statistically significant

Table 4: Factors associated with DPN in MNSI clinical examination version (n=38)

Factors	DPN Present N=38 (%)	DPN Absent N=62(%)	Chi-square test	p-value (χ^2)	Unadjusted Odds Ratio (95% CI)
Age					
>55 years	34 (88)	36 (61)	11.06	<0.01*	6.13 (1.9-19.4)
≤55 years	04 (12)	26 (39)			Ref
Gender					
Male	25 (70)	33 (52)	1.52	0.217	1.69 (0.73-3.89)
Female	13 (30)	29 (48)			Ref
Locality					
Rural	30 (73)	42 (71)	1.46	0.22	1.78 (0.69-4.59)
Urban	08 (27)	20 (29)			Ref
Tobacco consumption					
Present	23 (62)	12 (21)	17.55	<0.01*	6.38 (2.5-15.8)
Absent	15 (38)	50 (79)			Ref
Alcohol consumption					
Present	02 (9)	08 (11)	1.52	0.216	0.37 (0.07-1.8)
Absent	36 (91)	54 (89)			Ref
Age of diagnosis of DM					
>45 years	34 (15)	40 (32)	7.62	0.04*	4.6 (1.4-14.9)
≤45 years	04 (85)	22 (68)			Ref
Co-morbidities					
Present	32 (88)	29 (47)	13.87	<0.01*	6.06 (2.2-16.5)
Absent	06 (12)	33 (53)			Ref

* = P-value <0.05 is considered to be statistically significant

Table 5: Multivariate analysis of the significant risk factors

Factors	MNSI patient interview version (n=34)		MNSI clinical examination version (n=38)	
	Adjusted OR (95% CI)	P- value	Adjusted OR (95% CI)	P- value
Age				
>55 years	0.24 (0.03-2.05)	0.197	0.43 (0.06-2.81)	0.382
≤55 years [#]	Ref		Ref	
Gender				
Male	1.24 (0.38-4.0)	0.719	-	-
Female [#]	Ref			
Tobacco consumption				
Present	6.72 (2.07-21.8)	0.002*	10.2 (2.8-36.5)	<0.01*
Absent [#]	Ref		Ref	
Age of diagnosis of DM				
>45 years	1.21 (0.15-9.44)	0.851	0.33 (0.04-2.34)	0.269
≤45 years [#]	Ref		Ref	
Co-morbidities				
Present	7.19 (1.93-26.7)	0.003*	5.78 (1.6-19.9)	0.006*
Absent [#]	Ref		Ref	

* = P-value <0.05 is considered to be statistically significant, # = Reference group

On Multivariate analysis

To eliminate the effects of confounding bias, we undertook multivariate logistic regression. Based on this analysis, the risk factors which were found to be associated with DPN were: **Tobacco consumption** (OR: 6.7, CI:2.07-21.8, P=0.002), **presence of co-morbidities** (OR:7.19, CI:1.93-26.7, P=0.003) in MNSI patient version and **Tobacco consumption** (OR: 10.2, CI:2.8-36.5, P=0.01), **presence of co-morbidities** (OR:5.78, CI:1.6-19.9, P=0.006) in MNSI clinical examination version.

DISCUSSION

The present study was conducted to determine the proportion and risk factors of diabetic peripheral neuropathy among Type II diabetes at using Michigan Neuropathy Screening Instrument (MNSI).⁷

The overall proportion of DPN was around one-third of the study population (34% in MNSI patient interview version & 38% in MNSI clinical examination version)) which is similar to the findings of the studies conducted in different parts of India.¹³⁻¹⁸ However, this is in contrast with the findings of the study conducted by Kulkarni V et al⁶, Bansal et al¹⁹, Solanki JD et al²⁰ and Dutta SJ et al²¹ in which the lower proportion was observed. The difference in findings could be attributed to different study settings, various classification systems to screen DPN and availability of better health services in the above-mentioned studies.

The proportion of DPN was found to be higher in studies conducted at Chandigarh⁹, Manipal¹¹ in which the proportion was more than half of the study population, which is also in congruence with studies conducted in different parts of the globe²²⁻²⁵. This may be attributed to usage of different scores to assess DPN. A high prevalence of DPN may lead to various complications, ranging from ulceration to amputation.

Age wise increase in proportion of DPN was observed in current study with similar findings being reported by various studies conducted in the past.^{6,9,11,13,23,26-30} As the age advances, there are physiological changes such as reduced nerve function, diminished vascular supply, and alterations in metabolic processes, all of which can contribute to an increased risk of diabetic peripheral neuropathy.

DPN was also found to be higher among patients who had diagnosed diabetes at the age of >45 years in our study. This aligns with the findings reported from previous studies conducted in India^{9,14-17,28,31} and abroad^{18,25-27,29,30}. If diabetes is diagnosed at an earlier age, its management will be better and complications like DPN can be decreased with good glycemic control.

On multivariate analysis, Presence of co-morbidities like hypertension, cardiovascular diseases, bronchial asthma, thyroid diseases & cerebral-vascular attacks showed significant association with DPN which is in confirmatory with the findings of previously reported studies.^{9,18,21,25,29-31}

Tobacco consumption is more among study participants and had showed significant influence on DPN in our study, the reason being consumption itself is high as well as we have included smokeless forms of tobacco. This is in variation with results of other studies.^{19,20,30,31} Not considering smokeless tobacco as a risk factor may be the cause for the variation in other study findings.

The probability of a person with DPN is tenfold more likely to be consuming tobacco as compared to the person without DPN which is in congruence with other studies.^{11,14,18,21,23,26,27} Smoking may intensify neurological symptoms associated with DPN, such as pain and tingling sensations. The combination of smoking and diabetes can result in a more pronounced impact on nerve function.³²

Significant association was not observed with other risk factors which were considered in our study like

gender, locality, marital status, consumption of alcohol, current medications for diabetes however these risk factors showed significant influence in other studies conducted elsewhere in the globe.^{6,9,11,13-15,17,19-21}

To the best of our knowledge, the present study is the first of its kind in this study setting as there is no published literature on proportion and risk factors of DPN, which one of the strengths of the current study and the other strength being employment of MNSI standard tool for screening DPN which can be easily administered by health care providers even at peripheral settings.

Blood glucose investigations including HbA1c would have provided a better insight into the glucose control of the participants. Present study was conducted at Gundlupet, which is a border taluk of Chamara-janagar district. Since it is a self-financial study and the facilities to conduct certain investigations were not available so, we couldn't inculcate these investigations in our study.

This study did not address certain potential confounding factors, such as musculoskeletal conditions and nutritional deficiencies and the authors are in concurrence that the present study findings cannot be generalized as the study participants were recruited using convenient sampling technique. These are some limitations of the present study.

CONCLUSION

The overall proportion of Diabetic Peripheral Neuropathy in the present study was more than one-third of cases with chronic diabetes. DPN was found to be more in rural areas in the current study. Tobacco consumption & presence of co-morbid conditions like hypertension, dyslipidaemia and stroke were found to be significantly associated with DPN. There is a need to conduct further research in this area to fill the gap and the present study is instrumental in this direction.

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